



DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0030]

State University of New York College of Environmental Science and Forestry; Notice of Intent to Prepare an Environmental Impact Statement for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (*Castanea dentata*) Developed Using Genetic Engineering

AGENCY: Animal and Plant Health Inspection Service, Agriculture (USDA).

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: We are announcing to the public that the Animal and Plant Health Inspection Service intends to prepare an environmental impact statement (EIS) evaluating the impacts that may result from the approval of a petition for nonregulated status for blight-tolerant Darling 58 American chestnut (*Castanea dentata*) from the State University of New York College of Environmental Science and Forestry. The trees have been developed using genetic engineering to express an oxalate oxidase enzyme from wheat as a defense against the fungal pathogen *Cryphonectria parasitica*, making Darling 58 American chestnut tolerant to chestnut blight. Issues to be addressed in the EIS include the potential environmental impacts to managed natural and non-agricultural lands, the physical environment, biological resources, human health, socioeconomics, federally listed threatened or endangered species, and cultural or historic resources. We are requesting public comments to further delineate the scope of the alternatives and environmental and interrelated economic issues and impacts to be considered in the EIS.

DATES: APHIS will consider all comments received on or before [Insert date 30 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to www.regulations.gov. Enter APHIS-2020-0030 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0030, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

The petition and any comments we receive on this docket may be viewed at www.regulations.gov or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799--7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1238; (301) 851-3892, email: cynthia.a.eck@usda.gov.

SUPPLEMENTARY INFORMATION:

Purpose and Need for the Proposed Action

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, “Movement of Organisms Modified or Produced Through Genetic Engineering,” regulate, among other things, the importation, interstate movement, or release into the environment of organisms modified or produced through genetic engineering that are plant pests or pose a plausible plant pest risk.

The petition for nonregulated status described in this notice is being evaluated under the version of the regulations effective at the time that it was received. The Animal and Plant Health Inspection Service (APHIS) issued a final rule, published in the *Federal Register* on May 18,

2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034),¹ revising 7 CFR part 340; however, the final rule is being implemented in phases. The new Regulatory Status Review (RSR) process, which replaces the determination of nonregulated status petition process, became effective on April 5, 2021 for corn, soybean, cotton, potato, tomato, and alfalfa. The RSR process is effective for all crops as of October 1, 2021. However, “[u]ntil RSR is available for a particular crop..., APHIS will continue to receive petitions for determination of nonregulated status for the crop in accordance with the [legacy] regulations at 7 CFR 340.6.” (85 FR 29815). This petition for a determination of nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020) as it was received by APHIS on January 21, 2020.

APHIS received a petition from the State University of New York College of Environmental Science and Forestry (ESF) (APHIS Petition Number 19-309-01p)² seeking a determination of nonregulated status for blight-tolerant Darling 58 American chestnut (*Castanea dentata*). The petition states that Darling 58 American chestnut is unlikely to pose a plant pest risk and, therefore, should not be regulated under APHIS’ regulations in 7 CFR part 340.

According to our process³ for soliciting public comment when considering petitions for determination of nonregulated status of regulated organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. On August 19, 2020, we announced in the *Federal Register* (85 FR 51008-51009, Docket No. APHIS-2020-0030) the availability of the blight-tolerant chestnut petition for public comment.⁴ We solicited comments on the petition for

¹ To view the final rule, go to www.regulations.gov and enter APHIS-2018-0034 in the Search field.

² To view the petition, go to <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>.

³ On March 6, 2012, APHIS published in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for organisms developed using genetic engineering. To view the notice, go to www.regulations.gov and enter APHIS-2011-0129 in the Search field.

⁴ To view the notice, supporting documents, and the comments that we received, go to www.regulations.gov and enter APHIS-2020-0030 in the Search field.

60 days to help us identify potential environmental and interrelated economic issues and impacts that APHIS should consider in evaluation of the petition. We received 4,320 comments on the petition from the academic sector, farmers, non-governmental organizations, nonprofit organizations, industry, Tribes, and unaffiliated individuals.

Comments in favor of the petition emphasized the positive environmental and socio-economic benefits of restoring American chestnut throughout its pre-blight range. Issues raised in the opposing comments included environmental impacts of the unconfined release of a forest tree developed using genetic engineering, impacts to native communities, human health and safety impacts of using a wheat gene, the need for long term studies, the potential for chestnut to be more susceptible to chestnut blight as well as other diseases, the potential for impacts to organic producers, impacts to trade, and general anti-biotech sentiments. APHIS evaluated all comments received on the petition. A full record of comments received is available online at www.regulations.gov (see footnote 4). As part of our evaluation of the petition and consideration of public comments, APHIS has determined that this proposed action has potential to significantly affect the quality of the human environment.⁵ As such, APHIS is deciding to prepare an environmental impact statement (EIS) in order to conduct the level of detailed and rigorous environmental analysis required to make an informed decision about the proposed deregulation of Darling 58 American chestnut.

The EIS is being prepared in accordance with: (1) National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) the Council on Environmental Quality's (CEQ) NEPA-implementing regulations (40 CFR parts 1500-1508), (3) USDA's NEPA-

⁵ Human environment means comprehensively the natural and physical environment and the relationship of present and future generations of Americans with that environment. Impacts/effects include ecological (such as effects on natural resources, and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic (such as the effects on employment), social, or health effects (see 40 CFR 1508.1).

implementing regulations (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Proposed Action and Alternative the EIS will Consider

The EIS will analyze the preferred alternative, approval of ESF's petition for a determination of nonregulated status for Darling 58 American chestnut, as well as the no action alternative, denial of the petition for nonregulated status. Both alternatives will receive APHIS' full consideration. APHIS has developed a list of topics for consideration in the EIS based on public comments on the petition, prior environmental assessments (EAs)/EISs for plants developed using genetic engineering, public comments submitted for other EAs/EISs evaluating petitions for nonregulated status, scientific literature on biotechnology, and issues identified by APHIS specific to American chestnut and other *Castanea* species. The following topics were identified as relevant to the scope of analysis: Action Area (Historic, Present, and Potential Future Range of American Chestnut); Physical Environment (Soil Quality, Water Resources, Air Quality and Climate Change); Biological Resources (Animal Communities, Plant Communities, Gene Flow and Weediness, Microorganisms, and Biodiversity); Human Health Considerations; Animal Health and Welfare; and Socioeconomic Considerations (Domestic Economic Environment, International Trade). In addition, potential impacts on threatened and endangered species, as well as adherence of the Agency's decision to Executive Orders, and environmental laws and regulations to which the action may be subject will also be examined.

Summary of Potential Impacts

APHIS anticipates the potential impacts of the proposed action could include impacts on the physical environment, biological resources, and socioeconomic impacts.

Anticipated Permits and Authorizations

Darling 58 American chestnut, if deregulated, could be cultivated to produce food or animal feed, subject to any Environmental Protection Agency's (EPA) and/or U.S. Food and

Drug Administration (FDA) requirements under the Coordinated Framework.⁶ For example, any human food or animal feed derived from Darling 58 American chestnut would be subject to the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq.*) and FDA requirements. ESF may voluntarily consult with the FDA to ensure compliance with the FFDCA.

Public Scoping Process

As previously discussed, APHIS seeks public comment on petitions deemed complete through notices published in the *Federal Register*. In accordance with our process, on August 19, 2020, APHIS solicited comments on the petition for 60 days and received 4,320 comments from the academic sector, farmers, non-governmental organizations, nonprofit organizations, industry, Tribes, and unaffiliated individuals.

APHIS is seeking additional public comment on this notice of intent to prepare an EIS to help identify potential alternatives, as well as relevant information, studies, and/or analyses that we should consider in evaluating the potential impacts of the proposed action on the quality of the human environment. Those who have already submitted comments on the ESF petition need not resubmit—we will consider these comments in development of the EIS. To promote informed NEPA analysis and decisionmaking, comments should be as specific as possible and explain why the issues raised are important for consideration in the EIS. Comments should include, where possible, references and data sources supporting the information provided in the comment. We encourage the submission of data, studies, or research to support your comments.

APHIS will accept written comments for a period of 30 days from the date of this notice. The petition is available for public review, and copies are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above.

Schedule for the Decision-making Process

⁶ See Coordinated Framework. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services, <https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/>.

As part of the decision-making process regarding the petition, we are preparing a plant pest risk assessment (PPRA) and the EIS that is the subject of this notice. We plan to complete the PPRA within 6 months, and the EIS and record of decision (ROD) within 2 years of the date of this notice. This schedule is tentative and subject to extension.

Once we have reviewed the comments received in response to this notice, we will prepare and make available a draft EIS for a review and comment for a period of 45 days. A notice for public comment on the draft EIS will be provided in the *Federal Register*, and the draft EIS and associated documents will be made available on www.regulations.gov.

The commenting and review process on the draft EIS will be conducted in accordance with CEQ's NEPA regulations. Comments will be invited from State, Tribal, and local governments and agencies, industry, environmental organizations, academia, and the public. APHIS will review all comments received on the draft EIS, provide responses to substantive comments, and incorporate relevant issues raised in the comments into development of a final EIS.

We will announce the availability of the final EIS in the *Federal Register* and file the final EIS together with comments and responses with the EPA, Office of Federal Activities, consistent with EPA's procedures and CEQ's filing requirements. The EPA will publish a notice in the *Federal Register* announcing the final EIS. APHIS will issue a ROD on the final EIS and petition 30 days after the EPA notifies the public that the final EIS has been completed and submitted. If necessary, APHIS may extend these timeframes.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 2nd day of August 2021.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

